Jo Anne Stokfisz
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September 26, 2000

Honorable Donna Shalala
Secretary of Human and Health Services
200 Independence Avenue, S.W. Room 615 F
Washington, D.C. 20201

Dear Secretary Shalala:

I am a small business owner in the State of Michigan, in five counties, providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the market place. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50 state effort by audiologist to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20% of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,

Jo Anne Stokfisz

DRAFT PROPOSED FDA HEARING AID RULE INCREASES COST; REDUCES ACCESS AND UTILIZATION

September 2000

A. Background

- Hearing Aids Underutilized. Approximately 28 million Americans suffer from hearing loss. Only 5.8 million wear hearing aids. Most could benefit from hearing aids, but do not seek them. Barriers include: stigma, stubbornness, slow incremental loss, unreimbursed cost, inadequate training in use, geographic inaccessibility, etc.

- Three Groups of Qualified Dispensers. Hearing is tested, and aids are fitted and dispensed by three groups of qualified, licensed and certified hearing health professionals: physicians-otolaryngologists and otologists; audiologists and hearing aid specialists (HAS).

- Most Hearing Loss Cannot be Treated Medically or Surgically. The majority of hearing loss (more than 90% according to AARP) is sensorineural and medically untreatable (degeneration of cochlea, cilia or auditory nerve) due primarily to the aging process or long-term exposure to excessive noise.

- FDA Restricts Dispensing Practices. Current FDA regulations preempt States; require disclosure that patients should see physicians before purchase; and allow written "waiver" of medical evaluation.

- Proposal Would Defer to States. FDA's draft proposed rule would reportedly "abandon the field" and allow individual states to determine the conditions for dispensing, including whether to permit waivers of medical evaluation. Many states have supported mandatory "unwaivable" physician evaluation, or audiologists as "gatekeepers."

- States Sought Mandatory Medical Exams. Existing law allows states to petition FDA for an exception from its rule if they seek a stricter dispensing standard. States petitioned FDA to eliminate the medical waiver and require physician examinations prior to purchase. FDA denied those exemption requests reasoning that patients should be entitled to utilize other qualified hearing health professionals.

- Proposal Would Initiate State Action. Publication of even a proposed rule granting states additional authority over medical device dispensing would likely lead to a flurry of state legislative and regulatory activity requiring medical examinations, or requiring expensive and unnecessary diagnostic testing by audiologists.

B. Position of International Hearing Society (IHS)

- Physician Should be Consulted. Prospective users of hearing aids should all be under physician's care, and usually are.

- Pre-Purchase Medical Exam Unnecessary. Requiring consumers seeking hearing tests to consult a physician less than ~~60 days~~ 6 months before buying a hearing aid could increase the cost of hearing health, diminish use of qualified allied health professionals, reduce utilization further and not improve public health. The bulk of physicians are not trained to detect or measure hearing loss, or fit hearing aids, and more than 90 percent of candidates for hearing aids don't have a treatable medical condition anyway.

- Federal Uniformity Should be Preserved. While the current law could be modernized or streamlined, it is better left unchanged. FDA should not abdicate its responsibility to the states, but should preserve federal consistency and uniformity related to use of medical devices.

- "Red Flag" System Should be Adopted. The IHS and the American Academy of Otolaryngology-Head and Neck Surgery (AAO), together representing 2/3 of the hearing health team, proposed a superior "red flag system" where all qualified hearing health providers screen patients for red flag otologic signs of treatable medical conditions first, and then medical referral is required if a red flag is present. This system acknowledges that medical treatments are unavailable for most patients with hearing difficulties, but identifies the patients physicians can treat most successfully.

- Mail-Order Sales Must Comply. FDA has continued to permit the mail-order sale of hearing aids where testing, proper measurement, fitting and training on the use of the aids cannot occur. Permitting mail order sales, without requiring the same dispensing practices required of all other dispensers, undermines the expressed purpose of a revised regulation.

- Eliminate Misleading Advertising. Finally, FDA has been lax in seeking compliance action against the false and misleading advertising by manufacturers of "hearing aid like" or "super hearing devices." Consumers of these cheaper products are frequently disappointed with their performance and, therefore, do not seek bona-fide devices.

C. Rationale

- FDA Traditionally Preempts State Device Authority. FDA has, until this point, set a uniform standard for the dispensing of medical devices, preempting state law and the inevitable inconsistencies in the quality of care that would arise from giving state licensing boards discretion to determine conditions of use. Federal preemption should be maintained in the interest of consistency, access, cost and maintaining a level playing field between licensed and qualified hearing health professionals. There is no

compelling reason to cede this authority to the states.

- Consequences Not Analyzed Sufficiently. A proposed rule should not be rushed through the clearance process at the end of an Administration without adequate review. The consequences of the new approach reportedly suggested by FDA have not been analyzed sufficiently.

- Results in Unnecessary Physician Examinations. History has demonstrated that many states would restrict or eliminate the use of waivers. Patients could be required to undergo comprehensive diagnostic medical hearing examinations before obtaining hearing aid evaluations. This would "put the cart before the horse" unwisely requiring all patients to undergo expensive medical procedures which will help just a small percentage. Only then would patients be permitted by many states to proceed to the testing, and possible fitting of a hearing aid, from which most would likely benefit.

- Additional Testing Not Required. Hearing health professionals (physicians, audiologists and HASs) licensed and certified by the states are all qualified to conduct the hearing testing required to measure hearing loss and fit the appropriate medical device. Additional "audiologic" or "diagnostic" testing should only be required if a readily detectable red flag symptom of a treatable medical condition is present (e.g., bleeding from ear, dizziness, rapid hearing loss, loss in only one ear, etc.).

- Increases Costs and Reduces Access. In the absence of the Federal waiver provision, audiologists are poised to persuade state licensing boards to require diagnostic testing that only audiologists are licensed to perform. FDA would, therefore, permit states to increase the required battery of preliminary (and expensive) tests, while restricting the number of practitioners who can perform them. The cost of obtaining hearing aids would be increased while reducing their availability (since audiologists are concentrated in urban centers). This will only exacerbate the present underutilization of the devices.

- Reduces Already Low Utilization. State requirements that all consumers obtain physician hearing evaluations prior to purchase, or "audiological" testing, could cost each consumer $250-$500 more in unreimbursed testing and device costs according to studies conducted by the Lewin Group and the EOP Group. These increased costs, and an audiologist "gatekeeper" to sell the device following testing, will reduce already low utilization and potentially eliminate the HAS, a valuable component of the hearing health team.

- Proposal Should be Limited to "Red Flag" System. If FDA seeks to eliminate the medical waiver, it should initiate the "red flag system" designed by the physician-specialist dispensing community. Consumers are encouraged to seek hearing testing wherever they are most comfortable--doctor's offices, audiologist clinics or HAS facilities. All use questionnaires and screen for AAO-approved otologic "red flag"

symptoms before hearing evaluations. If any of the 10 designated "red flags" exist, the patient must be referred to a physician, preferably one specializing in diseases of the ear.

- Red Flag System More Flexible; Appropriate. Physicians, audiologists and hearing aid specialists are all qualified to screen patients for these "red flag" warning signs and conduct audiometric testing to detect and measure the extent of hearing loss. FDA should adopt this practical, more flexible position. Alternatively, it should grant state licensing boards the authority to designate the conditions for red flags that would require physician referrals.

- Mail-Order Sales Must Comply with Same Rules. FDA should require mail-order sales to comply with the same testing and fitting standards it applies to all other hearing aid dispensers.

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U.S. POSTAGE

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